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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,661	02/28/2002	Masatoshi Chiba	P21749	5687
7055 7590 05/29/2008 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER				
KOLKER, DANIEL E				
ART UNIT		PAPER NUMBER		
1649				
NOTIFICATION DATE		DELIVERY MODE		
05/29/2008		ELECTRONIC		

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MASATOSHI CHIBA,
Appellant

Appeal 2008-2764
Application 09/926,661¹
Technology Center 1600

Decided: May 27, 2008

Before CAROL A. SPIEGEL, MARK NAGUMO, and LORA M. GREEN,
Administrative Patent Judges.

SPIEGEL, *Administrative Patent Judge.*

DECISION ON APPEAL

¹ Application 09/926,661 ("the 661 application"), filed 28 February 2002, is said to be the national stage (35 U.S.C. § 371) of international application PCT/JP00/03506, filed 31 May 2000. PCT/JP00/03506 is said to claim priority benefit of Japanese Application 11151769, filed 31 May 1999. The real party in interest is said to be Mitsubishi Chemical Corporation (Amended Appeal Brief under 37 C.F.R. § 41.37(d) filed 15 February 2007 ("App. Br.") at 2).

I. Statement of the Case

This is an appeal under 35 U.S.C. § 134 from a final rejection of claims 1, 3, 4, and 6-16. Claims 22-28, the only other pending claims, have been withdrawn from consideration. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

The subject matter on appeal is directed to a lyophilized preparation containing a hepatocyte growth factor ("HGF"). Claim 1 is illustrative and reads (App. Br. 29):

1. A lyophilized preparation comprising a hepatocyte growth factor, a stabilizing agent comprising arginine, lysine, histidine, glutamine, proline, glutamic acid, or aspartic acid, or a pharmacologically acceptable salt thereof, for preventing formation of an aggregate of the hepatocyte growth factor, sodium chloride, and a buffering agent, which is prepared from an aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL.

In response to an election of species requirement in the Office Action of June 28, 2005, Appellant elected arginine as the stabilizing agent (App. Br. 4). Thus, preparations containing arginine are before us.

The Examiner has relied upon the following references² of record as evidence of unpatentability:

Tanaka (Tanaka US Pub)	US 2001/0051604	Dec. 13, 2001
Nakamura	EP 456 188 A1	Nov. 13, 1991
Tanaka ³	WO97/02832	Jan. 30, 1997

² No references to *et al.* are made in this opinion.

³ The Examiner found that Tanaka US Pub is the national stage entry of Tanaka and, therefore, a proper English translation thereof (Ans. 7).

The issues on appeal⁴ are whether

(a) claims 1, 3-4, 6-9, and 12-15 are anticipated under 35 U.S.C. § 102(b) by Nakamura;

(b) claims 1 and 16 are anticipated under 35 U.S.C. § 102 (b) or would have been obvious under 35 U.S.C. § 103(a) over Nakamura; and,

(c) claims 1, 3, 4, and 6-16 would have been obvious under 35 U.S.C. § 103(a) over Nakamura in view of Tanaka.

II. Discussion

A. Legal principles

Claimed subject matter is anticipated by the teachings of a reference only if the claimed subject matter is identically disclosed or described by the teachings of the reference. *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). To be anticipated, the claimed subject matter must be disclosed "clearly and unequivocally" in the reference. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972).

On the other hand, under 35 U.S.C. § 103, claimed subject matter may be unpatentable where a limited number of options is provided by the reference and one skilled in the art would have had a reason to select any one of the options for the purpose of obtaining the result reported in the reference. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007); *Merck & Co., Inc. v. Biocraft Labs, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989).

Appellant does not dispute the Examiner's finding (App. Br. 20). We cite Tanaka US Pub as the English translation of Tanaka in this Decision.

⁴ The final rejection of claim 11 under 35 U.S.C. § 112, ¶2 (indefinite) was withdrawn by the Examiner in an Advisory Action mailed 8 June 2006 (App. Br. 5; Examiner's Answer mailed 25 June 2007 ("Ans.") at 2).

B. Analysis

The dispositive point of contention between Appellant and the Examiner is whether Nakamura describes the claimed subject matter, particularly inclusion of arginine as required by all the appealed claims, "without any need for picking, choosing, or combining various disclosures" (App. Br. 10). We have not found it necessary to evaluate separate arguments for patentability that Appellants have raised with regard to certain dependent claims.

1. anticipation of claims 1, 3, 4, 6-9, and 12-15 by Nakamura

Nakamura describes preparing an injectable solution by dissolving HGF in suitable buffers (Nakamura 9:46-51) and freeze-drying (lyophilizing) the solution for storage (*id.* 10:7-13). According to Nakamura, the solution may also contain other additives

such as stabilizers, excipients, dissolution-promoters, adsorption-preventors and antioxidants, and examples thereof include, for example, sugars such as mannitol and glucose, amino acids such as glycine, alanine, lysine and arginine, proteins such as albumin, alcohols such as ethylene glycol and glycerol, hydrophilic polymers such as polyethylene glycol, inorganic salts such as NaCl, organic salts such as sodium citrate, surfactants such as Polysorbate 80 and reducing agents containing sulfur, which may be used alone or in combination. [*Id.* 9:52 through 10:6.]

Nakamura exemplifies five aqueous HGF solutions, none of which contain arginine (*id.* 14:25 through 15:11).

The Examiner has not specifically identified an embodiment in Nakamura which describes a solution containing HGF, arginine, sodium

chloride, and a buffering agent which is lyophilized as required by independent claims 1 and 3. The Examiner has not shown where Nakamura provides a pattern of preferences which describes the claimed invention without the necessity for judicious selection from various disclosures in Nakamura. Since, as Appellants argue (e.g., App. Br. 12-13), there are a number of different additives having diverse effects to choose from, we find that one of ordinary skill in the art would not necessarily have found the lyophilized preparations of claims 1, 3, 4, 6-9, and 12-15 to be clearly and unequivocally described or disclosed by Nakamura. Consequently, we reverse the rejection of claims 1, 3, 4, 6-9, and 12-15 as anticipated under § 102(b) by Nakamura.

2. anticipation/obviousness of claims 1 and 16 over Nakamura

According to the Examiner, Nakamura describes the preparation of claim 1 but "is silent as to whether or not the stabilizing agent arginine is present 'in an amount sufficient to prevent HGF aggregate formation' as recited in claim 16" (Ans. 6). The Examiner concludes it is appropriate to shift the burden to Appellant to distinguish the claimed subject matter "from that of either claim 1 or . . . Nakamura" (Ans. 7).

We reiterate our finding that claim 1 is not anticipated by Nakamura. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The Examiner has not provided a sufficient basis for concluding that the subject matter of claim 1 or 16 is obvious over the teachings of Nakamura.

Consequently, we reverse the rejection of claims 1 and 16 under § 102 (b) or § 103(a) over Nakamura.

3. obviousness of claims 1, 3, 4, and 6-16 over Nakamura and Tanaka

The Examiner relies on the rejection of claims 1, 3, 4, 6-9, and 12-16 as anticipated by, or in the alternative, as rendered obvious by, Nakamura (Ans. 7). The Examiner notes that “Nakamura does not teach pH of the solution before lyophilization in the range of 5 to 6.5.” (*Id.*) The Examiner relies on Tanaka as teaching HGF solutions with pHs in the range of 5 to 6.5 (Ans. 7). Since the Examiner has not provided a sufficient basis for concluding the subject matter of claim 1 is obvious over the teachings of Nakamura, we reverse the rejection of claims 1, 3, 4, and 6-16 under § 103(a) over Nakamura and Tanaka.

III. Order

Upon consideration of the record and for the reasons given, it is ORDERED that the Examiner's decision to reject claims 1, 3-4, 6-9, and 12-15 under 35 U.S.C. § 102(b) as anticipated by Nakamura is REVERSED;

FURTHER ORDERED that the Examiner's decision to reject claims 1 and 16 under 35 U.S.C. § 102 (b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Nakamura is REVERSED; and,

FURTHER ORDERED that the Examiner's decision to reject claims 1, 3, 4, and 6-16 under 35 U.S.C. § 103(a) as obvious over Nakamura in view of Tanaka is REVERSED.

REVERSED

Appeal 2008-2764
Application 09/926,661

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